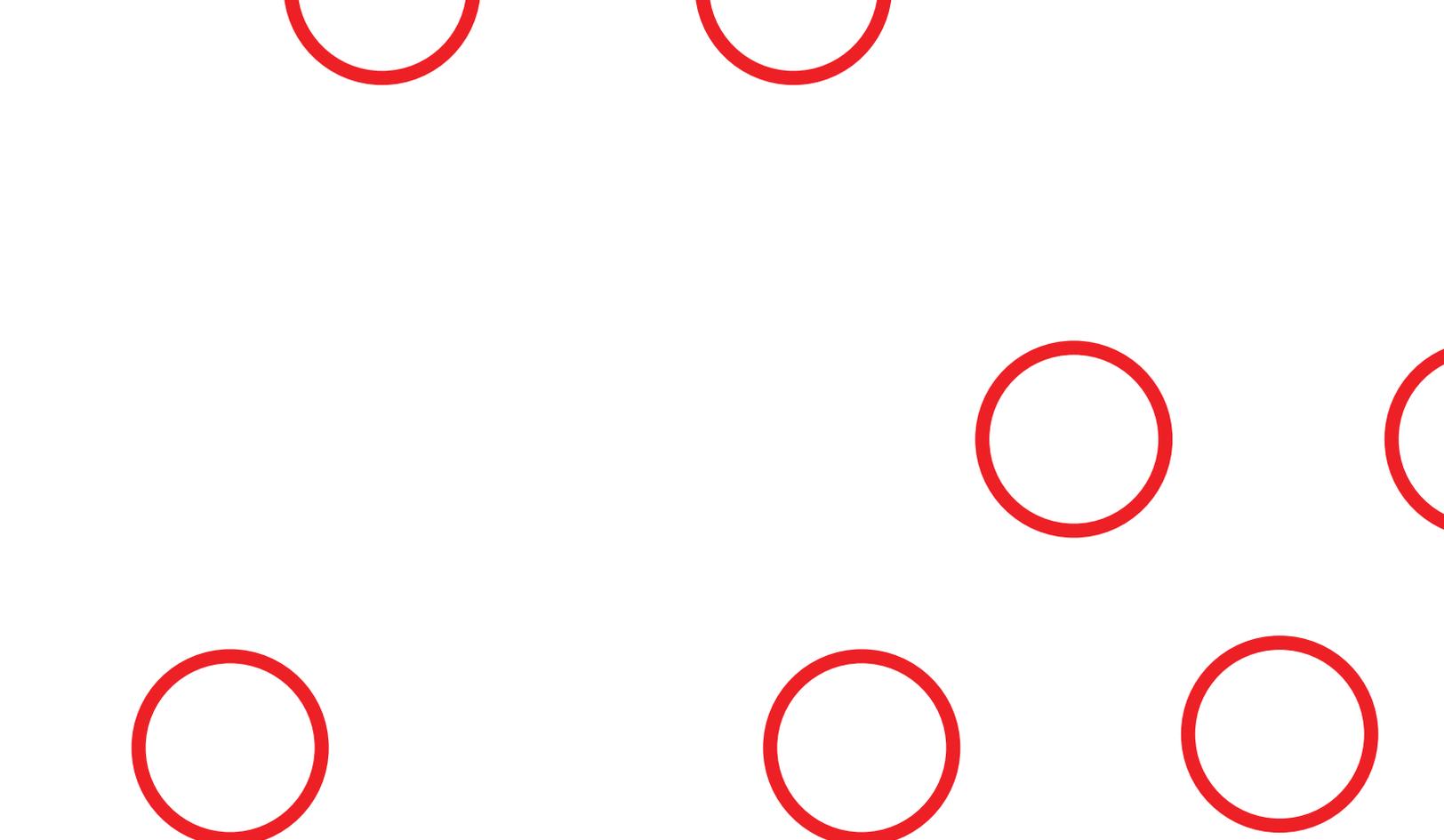


LASER THERAPY FOR BETTER CLINICAL OUTCOMES



**TAKE
CONTROL**

The top half of the page features several red circles of varying sizes and positions, some partially cut off by the edges of the frame. There are two circles at the very top, one in the middle-left and one in the middle-right. Below them, there are three circles in a horizontal row, and one more circle to the right of the middle-right circle in the row above.

About Laser Therapy
Role of Mitochondria
Physiological & Clinical Effects
Classes of Laser Therapy
Treatment Plan
Therapeutic Platforms



What is Laser Therapy?

Laser Therapy is known by many terms, including cold or low-level laser therapy (LLLT). Recently, experts have chosen photobiomodulation therapy (PBMT) as a more accurate term that describes the therapeutic use of red and near-infrared wavelengths of light energy from laser OR light emitting diodes (LEDs) that interact with photoreceptors. These produce photochemical reactions that have a positive effect on cellular metabolism and recovery from damage and inflammation. BIOFLEX is the only laser therapy company that utilizes powerful Class 3b lasers together with large surface arrays of bicolour LEDs that affect a large volume of circulating blood as well as underlying tissues resulting in both a powerful systemic and direct photobiomodulation effect. The overall clinical effect of targeting both the injured/diseased tissues as well as the surrounding circulatory system is an unsurpassed accelerated healing response and decrease in pain, inflammation, edema and associated symptoms.

Compared to other treatments, PBMT improves cellular metabolism and tissues healing. In this way, it can act synergistically with manual therapies and other modalities to help patients recover from musculoskeletal and peripheral nerve injuries with decreased symptoms, less scar tissue, accelerated cell regeneration and improved function.

Advantages of Laser Therapy

- + Highly effective
- + No known side effects
- + Very few contraindications
- + Directly targets injured/diseased cells
- + Indicated for nearly all conditions

Light Spectrum in Laser Therapy

The effectiveness of wavelengths of light with respect to photobiomodulation therapy can be characterized by the action spectra of the target photoacceptors (e.g. cytochrome c oxidase), that determine the positive biological responses such as increased metabolism, cellular regeneration and immunomodulation. The most clinically effective wavelength ranges are in the red (630-680 nm) and near infrared spectra (810-840 nm). Wavelength is one critical parameter of light among other factors such as dosage or energy density (J/cm²), treatment time and light delivery in pulses (cycles per second or Hz) in determining the efficiency of absorption, depth of penetration and ultimately the clinical outcomes. The effects of photobiomodulation are cumulative and can be clinically evident immediately after treatment or over a period of days.

Red Light

Since the introduction of the He-Ne laser (632.8 nm) in the 1960s, the positive effects of red light wavelengths ($\lambda = 630-680$ nm) have been established both in vitro and in human clinical trials. These wavelengths are highly absorbed by cytochrome c oxidase, one of the terminal enzymes in the electron transport chain responsible for the creation of ATP. Cells and tissues under metabolic stress due to injury or disease will repair and recover much faster when exposed to these red wavelengths as a direct result of increased ATP production and increased cellular metabolism.

Red wavelengths are also absorbed to some degree by other photoacceptors in the skin including hemoglobin and melanin which limits the effective depth of penetration to the subcutaneous regions of the body (approximately 1 cm). Other wavelengths like violet and blue are so highly absorbed by skin photoacceptors that they barely penetrate the skin (1-2 mm) and thus are not used in Laser Therapy with the exception of treating superficial skin conditions like acne.

Red wavelengths principally in the 630-680 nm range are very beneficial for treating conditions that are relatively superficial such as subcutaneous bursitis, skin conditions like acne, psoriasis, hair loss and eczema as well as wounds and chronic ulcers. The large network of capillaries located in the subcutaneous region will also absorb red wavelengths resulting in a powerful immunomodulating effect by activated white blood cells, stem cells and platelets. This is called a systemic or remote effect and it produces an anti-inflammatory and healing effect that is circulated by the activated white blood cells to injured and diseased tissues deep to the injured area. Even though red light does not penetrate deeply, it can still be a very powerful healing wavelength for deeper tissues provided the dosage of light is adequate. This explains why longer treatment times provide a greater therapeutic effect as a result of stimulation of a larger volume of blood by light. The more blood that is stimulated the stronger the systemic effect of photobiomodulation.

A final benefit of red wavelengths is their ability to cause analgesia and immediate pain relief for the patient. Roberta Chow and other researchers discovered evidence that higher dosages of light energy, especially the red wavelengths, can inhibit superficial nociceptors (pain nerve fibres) leading to inhibited translation of pain centrally. Photobiomodulation affects axonal flow, cytoskeleton organization, and decreased ATP in neurons that transmit pain. These researchers noted the effects are reversible with no side effects or nerve damage.

The BIOFLEX flexible array alternates between red and infrared light to increase the benefits of every treatment.

Near Infrared Light

Near infrared wavelengths are also absorbed by cytochrome c oxidase and other photoreceptors that result in positive effects on cellular physiology. Tiina Karu was the one of the key researchers to establish the photoabsorption spectra of these photoacceptors as well as the ranges of wavelengths that result in optimal photobiomodulation. She observed near infrared wavelengths in the ranges of 810-840 nm were most active, making them more effective for deeper lying injuries and conditions associated with musculoskeletal conditions.

These near infrared wavelengths are much less absorbed by hemoglobin and other photoacceptors that prevent light from penetrating more deeply. As a result, light in the range of 810-840 nm are considered to be the most transparent of the wavelengths used in photobiomodulation therapy allowing for much deeper effective penetration of 3-7 cm. The actual clinical effective depth of penetration varies as a result of factors like skin colour, tissue density, power, treatment time and using contact technique.

Tissues like bone, tendon, muscle, adipose and ligament vary with respect to how much light can effectively penetrate and accumulate to a dosage high enough to cause a photobiomodulation effect. When trying to elicit a direct photobiomodulation effect on these types of tissues, near infrared wavelengths (810-840 nm) are the most effective and are the “go to” wavelength range to heal these deeper tissues. Using greater power is one way to increase the dosage more quickly in these deeper tissues. However, as power increases so does the potential for an inhibiting thermal effect. Of course higher power also means shorter treatment times which results in fewer target photoacceptors being stimulated. Research has shown longer illumination times result in greater therapeutic effects. The consensus on how to achieve an optimal photobiomodulation healing effect is a balance of high enough power with longer treatment times.

Near infrared Laser Therapy is effective in the treatment of deeper lying tissues and has shown to be beneficial in treating a wide range of musculoskeletal conditions.

Role of Mitochondria

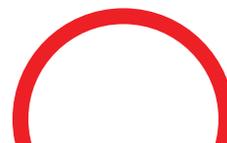
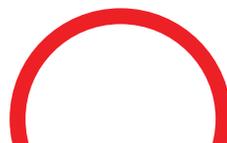
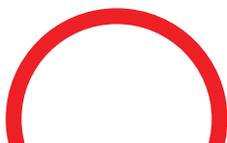
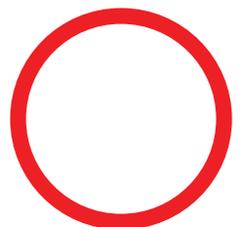
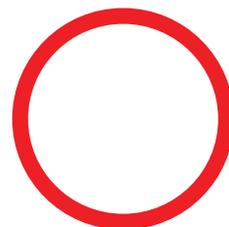
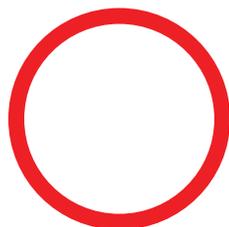
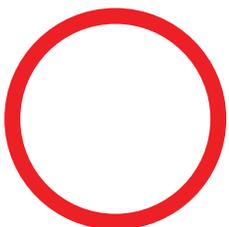
Approximately 90% of cellular energy requirements (ATP) are generated within the mitochondria. When cells and tissues are injured or inflamed, the ability to generate ATP is impaired resulting in slow tissue healing and long lasting symptoms.

Injuries, diseases and many conditions result in an influx of white blood cells that secrete pro-inflammatory chemical mediators (cytokines). This inflammatory reaction results in pain, edema and other symptoms experienced by the patient. Excessive and long lasting inflammation can occur which prolongs recovery and may lead to incomplete healing or even chronic symptoms. One of the by-products of inflammation is an increase in intracellular nitric oxide (NO).

How Photobiomodulation Affects Mitochondria

Increased NO due to inflammation preferentially binds to copper and iron subunits in cytochrome c oxidase preventing oxygen from binding. The result is decreased mitochondrial aerobic respiration and less ATP for all cellular functions including calcium signaling, cell growth, differentiation and cell cycle control.

Prolonged absorption of red and near infrared wavelengths in optimal dosages breaks hydrogen bonds between NO and copper and iron allowing for restoration of aerobic respiration and increased ATP production. The release of NO results in localized vasodilation and the secondary and tertiary events as a result of increased ATP activates the sodium potassium pump and signals cytoprotective proteins. The overall effect of photobiomodulation includes increased cell and tissue repair and regeneration, prevention of apoptosis (death), increased circulation and decreased inflammation.



Pulsed Light

Pulsing light in photobiomodulation therapy is one of the least understood parameters, yet has been shown to positively affect therapeutic efficacy. When light exits a diode it can be in a steady stream referred to as continuous wave or it can be modulated by pulsing at a set frequency from 1 to many thousands of cycles per second (Hz).

Pulsing light can be utilized to elicit a greater clinical response and substantial research supports this claim. It has also been shown to have benefits including:

- + Maximize biostimulatory effects
- + Minimize potential phototoxic effects during treatment of deeper tissues
- + Target specific cells based on their mitochondrial activity and ATP consumption
- + Increased depth of penetration of light through tissues
- + Decreased local transient heating of molecules

The use of frequency modulated light as part of the application of photobiomodulation therapy is a complementary parameter to continuous wave and stimulates cellular response, tissue healing, and overall clinical outcomes. Having the ability to customize different frequencies ensures the clinician has all the tools necessary to provide individual-based Laser Therapy.



Physiological and Clinical Effects

Cells and tissues that are injured or diseased have a slower metabolism as a result of higher levels of intracellular nitric oxide that inhibit mitochondria and cell functions.

Light energy in red and near infrared wavelengths are absorbed by mitochondria causing nitric oxide to be displaced. The net result is increased metabolism that results in accelerated cell and tissue repair and regeneration. Some examples include:

Angiogenesis & Neovascularization

Increased endothelial cell replication results in an increased capillary network and oxygenated blood to the injured tissue that accelerates tissue healing.

Muscle Repair & Regeneration

Repair of damaged muscle fibres and increased myogenic reserve cells leads to faster and more complete regeneration of muscle tissue.

Nerve Regeneration

Proliferation of growth factors encourages neuronal sprouting and myelin formation for optimal nerve recovery.

Bone Formation

Proliferation of osteocytes and remodeling of bone extracellular matrix results in accelerated callus formation and bone repair.

Collagen Production

Improved alignment, remodelling and maturation of collagen reduces scar and adhesion formation.

Inflammation & Edema

Decreased pro- and increased anti-inflammatory cytokines (e.g. interleukins) and lymphatic vasodilation helps to resolve inflammation and edema.

Cartilage Production

Increase in chondrocyte regeneration and collagen production allows for improved cartilage repair and joint function.

CLASS III VS. CLASS IV LASERS

Class 3b		5-500 mW Athermal	Lower energy and longer treatment duration optimizes healing and anti-inflammatory effects.
Class 4		>500 mW Thermal	High energy and longer wavelengths result in tissue heating, less penetration and inhibition of photobiomodulation.

The medical subject headings (MeSh) for Laser Therapy is now called photobiomodulation therapy (PBMT). Light emitting diodes (LEDs) and other sources of light have been proven to be clinically effective so referencing only lasers is not accurate anymore. The definition of PBMT mentions that if lasers are used they must be less than 500 mW to avoid a thermal reaction and inhibition of healing. Thus, any single laser diode with the goal of photobiomodulation should be a Class 3b when contacting the skin to ensure optimal penetration and provide enough stimulatory healing energy but not cause thermal tissue damage.

There is much confusion when Class 4 lasers are used for rehabilitation and are marketed as photobiomodulation therapy. Class 4 Laser Therapy (known as high intensity laser therapy or HILT) generally targets water to heat tissues resulting in a temporary analgesic effect but not a photobiomodulation effect that stimulates healing. There is no MeSh term for HILT as it is poorly researched.

The most common wavelength for Class 4 Laser therapy is 980 nm as it is highly absorbed by water molecules resulting in heat build-up – similar to far infrared lamps used to warm food at a restaurant. The power is so high that to avoid burns the laser diode cannot directly make contact with the skin and must be constantly moved. The therapeutic effect is analogous to using a deep heating pad.

Sometimes Class 4 Laser therapy uses red or near infrared wavelengths similar to that used in PBMT. In this case a very wide beam creates a large surface area which is held a distance away from the skin along with constant movement to avoid burns. This results in similar power densities (mW/cm²) and dosages used for photobiomodulation with Class 3b or LEDs but up to 85% of light is reflected. Thus, very little light is left to enter the skin causing poor tissue penetration. Interestingly, nearly all PBMT clinical research references the use of the contact technique where Class 3b lasers or LEDs touch and push into the skin in order to decrease reflection and maximize light penetration. This can never be achieved with Class 4 laser diodes.

Proponents of Class 4 lasers often claim that a larger area can be treated much faster. The flexible BIOFLEX Duo+ array is not only able to treat a large target area but is *hands-free* unlike all Class 4 laser devices.

Photobiomodulation requires enough dosage to stimulate healing but when too much is used there is no effect. This phenomenon is known as the biphasic dose response curve or the Arndt-Schultz Law. An example of this is the systematic review and meta-analysis on Laser Therapy for tendinopathies by Tumilty et al. His research revealed that most clinical studies were positive and those that were the negative were the result of dosages that were much higher than those recommended by guidelines. Higher dosages marketed by Class 4 Laser therapy devices are clearly not effective which is why evidence-based guidelines reference Class 3b lasers and not Class 4. Most clinicians are rightly confused about which Laser or light source to use and which dose or technique that will be effective.

Laser Therapy is not about heat but photochemical reactions that result in positive changes to cellular physiology. As for the high power, it causes no increase in the penetration depth. It is true that high power quickly produces more photons at the surface of the skin, but this is not necessarily beneficial. Studies have shown that low doses and long duration are more effective for healing and the reduction of inflammatory processes in such conditions as arthritis, whereas high power and short time are inhibitory, which can temporarily slow the pain transmission in nerves providing a temporary analgesic effect. While this may be a useful option in situations of acute pain, the healing effects of this higher power are muted. An analgesic effect can also be achieved using high dosages of class 3b without the risk of burns.

A Class 3b laser is safer and can be used with both contact and pressure. Thus more light can enter the tissue since blood, being the main absorber of the light, is reduced in the area and the light can more easily penetrate the tissue. Pressure will cause the laser probe to be closer to the target resulting in an even more powerful direct photobiomodulation effect.

Class 4 lasers are just too powerful to provide the healing effects of photobiomodulation associated with suitable Class 3b lasers and LEDs at a much lower cost.

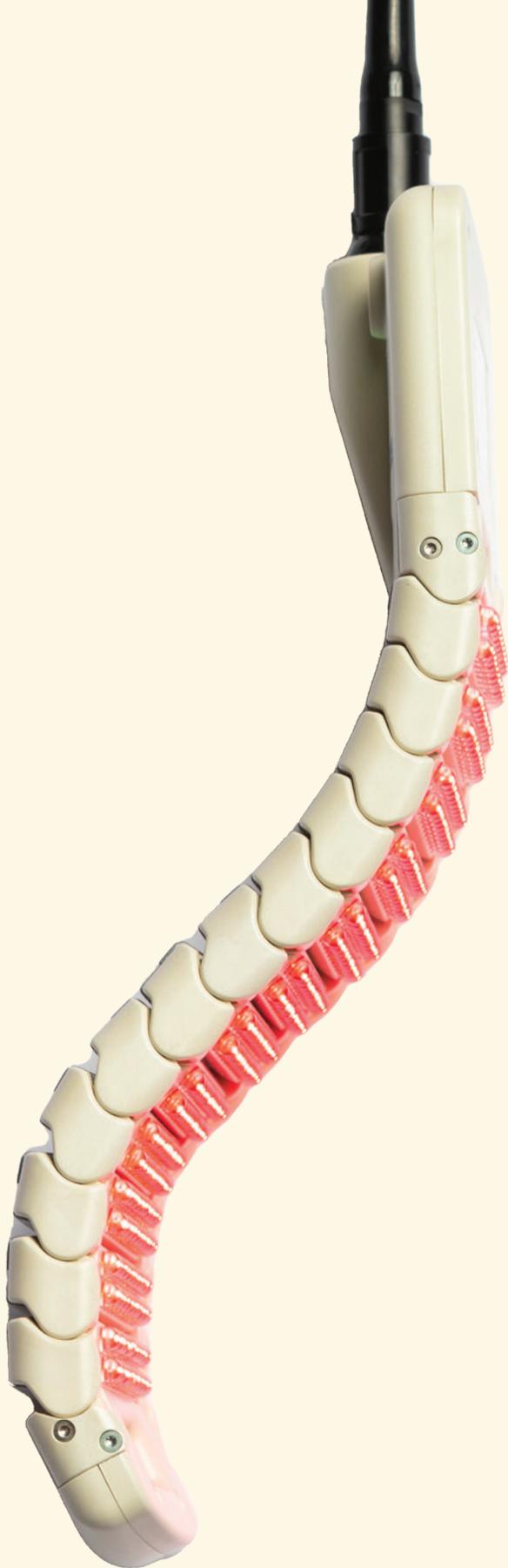
Treatment Plans

BIOFLEX Laser Therapy can be safely administered shortly after an injury in order to accelerate healing and decrease the inflammatory process. The sooner it is initiated the sooner patients will recover. Longstanding chronic conditions are the most challenging and often require photobiomodulation with varying parameters like duty cycle, frequency (pulses per second) and treatment time to provide optimal ongoing effective therapy. BIOFLEX Practitioner+ software includes clinically developed protocols, but also allows the clinician to customize all these parameters for each protocol ensuring every patient is treated on an individual basis.

In acute conditions, treating patients daily for several days in a row initiates a strong photobiomodulation healing effect. This approach is particularly applicable in cases of trauma, herniated discs, and acute injuries. With no known side effects, BIOFLEX Laser Therapy can be your first line of treatment for acute patients when most other forms of manual therapy or modalities are not contraindicated.

As the patient responds and the acute phase diminishes, treatment is typically performed two to three times per week along with other synergistic therapies such as exercise and manual therapies. As symptoms continue to diminish and the patient is recovering well, treatment is usually decreased to one to two times a week until maximal medical recovery is achieved and the patient is released from care. The entire treatment plan with BIOFLEX Laser Therapy varies from a few sessions to several weeks of treatment depending on the diagnosis and severity of the patient's condition.

Chronic degenerative conditions like osteoarthritis often require weekly or bi-weekly maintenance therapy treatment to slow the progression of the disease, regenerate articular cartilage and decrease the chance of acute flare-ups. As always, appropriate clinical judgment will dictate the need for continuing therapy.



Length of Treatment

The first phase of treatment is hands free and is initiated with red light being emitted from the Duo+ array for 6-8 minutes. After a brief audible beep and pause, the same LEDs automatically emit near infrared light for another 6-8 minutes for a total time of 12-16 minutes. The total time may vary +/- a few minutes depending the anatomical location and condition being treated. Two, three or even four Duo+ arrays can be used simultaneously which will shorten the overall time for large anatomical areas like the lumbar spine, shoulder and hip regions. This first phase of treatment is hands-free once the Duo+ array is positioned, secured and turned on.

The second phase of treatment uses our Class 3b laser probe. The near infrared (830 nm) laser probe is the standard laser used as it allows light to penetrate the deepest into tissues while stimulating target photoacceptors. However, our red laser may also be used simultaneously to target superficial anatomical structures and nociceptor (pain) nerve fibres. The laser probes are administered by the clinician or assistant directly on the skin overlying the tissues that are most affected (e.g. injured, inflamed or causing pain). The total length of treatment time with the laser probe(s) varies from 3-10 minutes depending on the anatomical region being treated.

Therapeutic Platforms of BIOFLEX Laser Therapy

Musculoskeletal Injuries

The most common applications are muscle strains, ligament sprains, tendinopathies, cartilage tears, bursitis and other injuries to the musculoskeletal system. Whether it's a sports injury, overuse condition, or an accident, the goal of treatment is to accelerate the healing process and decrease symptoms which allows the clinician to initiate manual and exercise therapies much sooner.

Arthritis

Chronic progressive forms of joint degeneration can be effectively managed with BIOFLEX Laser Therapy. All of the arthritides from early to late stages will respond to treatment resulting in decreased pain, inflammation, stiffness and edema as well as improved function, range of motion and activities of daily living. The goal is to help better manage patients with chronic progressive arthritis. Research has even shown repair and regeneration of eroded hyaline cartilage when exposed to Laser Therapy.

Wound Healing

One of the earliest known indications of laser therapy is wound healing since light can easily penetrate the wound bed. BIOFLEX has proven to accelerate surgical wound healing, dermal ulcers including diabetic lesions and those secondary to compression and all other recalcitrant wounds. This approach results in increased angiogenesis, neovascularization, collagen secretion and decreased inflammatory exudate and provides epithelization of the wound, improved arterial perfusion, and regeneration of the local and regional tissues.

Nerve Healing

From diabetic neuropathy to discogenic radiculopathy to carpal tunnel syndrome, BIOFLEX Laser Therapy can accelerate nerve healing and decrease paraesthesia and nerve pain as a result of direct absorption of light. Many peer reviewed clinical trials and lab studies have proven Laser Therapy is an effective therapy for nerve healing and has no known side effects.

Other Conditions

The ability of light to be absorbed and stimulate the metabolism of any cell type allows Laser Therapy to be effective for a wide range of inflammatory or degenerative conditions. Peer reviewed research has proven Laser Therapy can effectively treat lymphedema, alopecia (hair loss), skin rejuvenation, scar tissue reduction, fibromyalgia, acne, eczema, psoriasis and many other inflammatory based diseases and conditions.





Proper mitochondrial function and ATP production are critical to the process of cell regeneration and accelerated repair of injuries and chronic conditions.

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Contact the team at BIOFLEX Laser Therapy for clarification and further information regarding the protocols prescribed in this document.

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